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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/591,185  | 06/08/2000  | Ronald M. Cook       | 061873-5002US       | 2668             |
| 43850   | 7590        | 11/01/2005           | EXAMINER            |                  |
| MORGAN, LEWIS & BOCKIUS LLP (SF)<br>2 PALO ALTO SQUARE<br>3000 El Camino Real, Suite 700<br>PALO ALTO, CA 94306 |             |                      | EPPS FORD, JANET L  |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1633                |                  |

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/591,185

**Applicant(s)**

COOK, RONALD M.

**Examiner**

Janet L. Epps-Ford, Ph.D.

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-42 and 44-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-61 is/are allowed.
- 6) ☒ Claim(s) 32-42 and 44-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Drawings***

1. In the prior Office Action, the Drawings submitted by Applicants on 2/24/05 the examiner stated that the drawings were acceptable. However, upon further inspection of these drawings it is noted that the structures (linkers?) between the terminal nucleotide moieties and the fluorescent groups FAM and TAM are indiscernible. There is a structure between the terminal nucleotide and the FAM and TAM moieties, however the drawing does not clearly define what that structure is, or the print is so small that it is illegible.

Moreover, the drawings submitted 2/02/04 were never addressed by the examiner. It appears that the drawings submitted 2/02/04 were mistakenly labeled 09/591,185, and beginning with Figure 6 there is a different serial number listed on the Figures in the upper left-hand corner, specifically 10/004,122, issued as US Patent No. 6,737,422. Moreover, the substance of the drawings submitted 2/02/04 do not suggest a modification of the substance set forth in the previous drawing set filed 6-08-2000.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

2. Claims 32-42 and 44-49 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

3. Applicant's arguments filed 8-16-05 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that:

(1) There is support for a linker moiety which links the non-nucleic acid stabilizing moiety to the molecular energy transfer donor and/or the molecular energy transfer acceptor. Moreover, Applicants state that the examiner is objecting to the inclusion of the linker moiety in the structure because there is allegedly no support for such a linker. Applicants refer to page 25 of the specification to provide support for "linker groups."

The examiner agrees that there is support in the specification as filed for linker groups. However, the examiner maintains this objection on the grounds that the original structures of the claimed compounds and in the specification as filed does not provide support for the attachment of all forms of non-nucleic acid stabilizing moieties to the compounds of the invention via a linker moiety, wherein the linker serves to link a phosphate group with a nucleoside or nucleotide residues, and further wherein an additional linker group is linked to either a molecular donor or acceptor. Note the specific order or arrangement of the components of the formula set forth in claim 32. The general formulas set forth in claim 1 as originally filed or set forth in the specification as filed did not specifically set forth the role or position of a linker moiety within the context of these formulas.

(2) Applicants traverse on the grounds that there is ample support in the specification for stabilizing moieties other than the specific CHOL moiety recited in claim 50. In support for the teaching of stabilizing moieties other than CHOL, applicants make reference to page 12, line 6, wherein it states "In contrast to previous probes, the CAPS

of the invention utilize, for example, a hydrophobic-hydrophobic interaction between two or more stabilizing moieties to bring the donor and the acceptor into proximity." Moreover, Applicants make reference to pages 17-20 to support the assertion that the specification does in fact support the inclusion of stabilizing groups other than CHOL.

The examiner agrees that within the context of the generic structures set forth in original claim 1 and the specification as filed, there is definitely support for the introduction of the full range of non-nucleic acid stabilizing moieties as described in the specification as filed. However, with respect to the specific formula recited in original claim 50, there is no support for modifying this specific formula, particularly with respect to the stabilizing moiety.

(3) Applicants traverse on the grounds that Applicant recites specific limits as to what non-nucleic acid stabilizing groups are fairly encompassed by the claims. Applicants state that the specification defines what exactly constitutes a stabilizing moiety suitable for the practice of the invention, specifically at page 13, lines 16-22, wherein it recites:

In choosing stabilizing moieties, any two groups that exhibit an affinity for each other can be used to bring the donor and acceptor into the desired proximity. Presently preferred stabilizing moieties are those that meet four criteria: (1) the binding energy of the stabilizing moieties is preferably less than the hybridization energy between the probe sequence and its target sequence; (2) the stabilizing moieties are preferably not themselves quenchers; (3) the stabilizing moieties preferably do not interfere with hybridization of the probe to its target sequence; and (4) the stabilizing ligand/oligonucleotide conjugate is preferably cost-effective to manufacture and easily purified. (emphasis added).

According to Applicants each of these four criteria is readily calculated and/or determined by the skilled practitioner.

However, contrary to Applicant's assertions the instant claims are not limited to wherein the stabilizing moiety comprises the four characteristics mentioned above. The passage from the specification above, states that "*preferred*" stabilizing moieties are those that meet these criteria, the specification as filed does not state that all stabilizing moieties encompassed by the claims are limited to only those *preferred* stabilizing moieties described in the specification. The description of the stabilizing moiety provided above is therefore not limiting. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Although the examiner recognizes and agrees that within the context of the generic structure recited in original claim 1, there is support for the introduction of any non-nucleic acid stabilizing moieties as described in the specification as filed. However, there does not appear to be ample support for substituting the CHOL set forth in original claim 50 with the full scope of stabilizing moieties encompassed by the specification as filed, and since the specification as filed is not particularly limiting with regards to the definition of the term "stabilizing moiety," it is concluded that the specification as filed does not provide support for the structure as set forth in claim 32, and those claims dependent thereon.

The specification as filed, describes a single compound in which the stabilizing moiety CHOL is attached to the R2 and R3 groups of the structure and the chemical steps used to produce it (see Example 1). There is no teaching and/or suggestion to

modify the specifically disclosed formula set forth in original claim 50 to produce the structure set forth in instant claim 32.

4. The rejection of claims 32-42, and 44-61 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's arguments and/or amendment.

***Conclusion***

5. Claims 50-61 are allowable over the prior art searched. Claims 32-42 and 44-49 remain rejected under 35 USC 112, 1<sup>st</sup> paragraph for the reasons of record.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

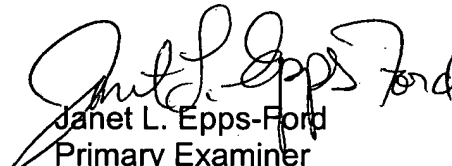
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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Janet L. Epps-Ford  
Primary Examiner  
Art Unit 1633

JLE